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PTO/SB/05 (4/98)
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	PT1443001
First Inventor or Application Identifier	George Wu
Title	Biocompatible Aqueous Solution for Use In Continuous Ambulatory Peritoneal Dialysis
Express Mail Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231

1. [X] * Fee Transmittal Form *(e.g., PTO/SB/17)* *(Submit an original and a duplicate for fee processing)*
2. [X] Specification [Total Pages 19] *(preferred arrangement set forth below)*
   - Descriptive title of the Invention
   - Cross References to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to Microfiche Appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
3. [ ] Drawing(s) *(35 U.S.C 113)* [Total Sheets]
4. Oath or Declaration [Total Pages]
   - a. [ ] Newly executed (original or copy)
   - b. [X] Copy from a prior application (37 C.F.R. § 1.63(d)) *(for continuation/divisional with Box 16 completed)*
     - i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

** NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).*

5. [ ] Microfiche Computer Program *(Appendix)*
6. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   - a. [ ] Computer Readable Copy
   - b. [ ] Paper Copy (identical to computer copy)
   - c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. [ ] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [X] Preliminary Amendment
12. [X] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
13. [X] * Small Entity Statement(s) *(PTO/SB/09-12)* [X] Statement filed in prior application, Status still proper and desired
14. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
15. [ ] Other: .....

16. **If a CONTINUING APPLICATION,** *check appropriate box, and supply the requisite information below and in a preliminary amendment:*
[X] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No: 08/558,472
Prior application information: Examiner M. Moezie Group / Art Unit: 1617

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

[X] *Customer Number or Bar Code Label* 23607 *(Insert Customer No. or Attach bar code label here)* *or* [ ] *Correspondence address below*

Name					
Address					
City		State		Zip Code	
Country		Telephone		Fax	

Name (Print/Type)	Marcelo K. Sarkis	Registration No. (Attorney/Agent)	37,015
Signature		Date	June 14, 2000

Burden Hour Statement: This form is estimated to take 0.2 hours to complete Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

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Patent & Trade Mark Agents
Canada, United States

Barrister & Solicitor
Ivor M. Hughes
Patent Agents
Neil H. Hughes, P.Eng.
Marcelo K. Sarkis, P.Eng.
Counsel
Alfred Schorr

Our Ref. PT1443001

June 14, 2000

Via Courier

The Commissioner of Patents
UNITED STATES PATENT OFFICE
2011 South Clark Place
Crystal Plaza 2, Room 1B02
Arlington, Virginia,
U.S.A. 22202

Dear Sir:

Re: Continuation Application Of Pending Prior
Application Serial No. 08/558,472
of George Wu, Paul Y. Tam and Ian W. French
for BIOCOMPATIBLE AQUEOUS SOLUTION FOR USE IN CONTINUOUS AMBULATORY PERITONEAL DIALYSIS
CUSTOMER NO. 23607

Please find enclosed herewith the following documentation for filing a continuation application under 37 CFR 1.53(d), of pending prior Application Serial No. 08/558,472 with the Commissioner:

(a) Utility Patent Application Transmittal;
(b) Fee Transmittal for FY 2000;
(c) Copy of Disclosure of United States Patent Application Serial No. 08/558,472 as originally filed;
(d) Copy of Claims 1-37 of United States Patent Application Serial No. 08/558,472 as originally filed;
(e) Copy of Verified Statement (Declaration) Claiming Small Entity Status;
(f) Copy of Declaration, Power of Attorney and Petition;
(g) Preliminary amendment, including new Claims 38-82;
(h) New Abstract.

Enclosed along with this material please find a cheque in the amount of **$609.00 U.S. dollars** which includes $345.00 for the base filing fee of a small entity, $39.00 for 1 independent claim over and above the three allowed, and $225.00 for 25 claims over and above the twenty claims allowed per application. If there is any deficiency or

surplusage of the fees enclosed for filing this Application, please obtain any such deficiency or credit the surplusage to Deposit Account 08-3255 and advise Applicants' Agent.

Also enclosed herewith is a stamped, self-addressed acknowledgment of receipt card which we request that you kindly acknowledge and return to this office at the earliest opportunity.

We thank the Commissioner for his cooperation in this regard and look forward to receiving filing data in this matter.

Respectfully submitted,

Marcelo K. Sarkis
Registration No. 37,015
Agent for Applicant

WKS*kdk
Enclosures

APPLICANT OR PATENTEE	:	GEORGE WU, PAUL Y. TAM and IAN W. FRENCH
ATTORNEY'S DOCKET NO.	:	PT-1143
SERIAL OR PATENT NO.	:	2,155,910
FILED OR ISSUED	:	August 11, 1995
FOR	:	A BIOCOMPATIBLE AQUEOUS SOLUTION FOR USE IN CONTINUOUS AMBULATORY PERITONEAL DIALYSIS

Verified Statement (Declaration) Claiming Small Entity Status (37 CFR 1.9(f) and 1.27(b)) - Independent Inventors

As below-named inventors, we hereby declare that we qualify as independent inventors as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled A BIOCOMPATIBLE AQUEOUS SOLUTION FOR USE IN CONTINUOUS AMBULATORY PERITONEAL DIALYSIS described in

[X] the specification filed herewith;
[ ] application serial no. , filed ;
[ ] patent no. , issued .

We have not assigned, granted, conveyed or licensed and are under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not b classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a non-profit organization under 37 CFR 1.9(e).

Each person, concern or organization to which we have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

[X] no such person, concern, or organization
[ ] persons, concerns or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CRF 1.27)

FULL NAME :
ADDRESS: :
[ ] INDIVIDUAL
[ ] SMALL BUSINESS CONCERN
[ ] NONPROFIT ORGANIZATION

We acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

INVENTOR GEORGE WU

First Name Middle Name Last Name

SIGNATURE : George Wu

DATE : Nov 9 1995

Month Day Year

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INVENTOR PAUL Y. TAM

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INVENTOR IAN W. FRENCH

First Name Middle Name Last Name

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CANADA, M2L 2M4

IN THE UNITED STATES PATENT OFFICE

Application Serial No.

Our Ref.: PT1443001
CUSTOMER NO. 23607

Applicants : George Wu
Paul Y. Tam
Ian W. French

Agent: Ivor M. Hughes,
Suite 200,
175 Commerce Valley Drive West,
Thornhill, Ontario
Canada L3T 7P6

Title : BIOCOMPATIBLE AQUEOUS SOLUTION FOR USE IN CONTINUOUS AMBULATORY PERITONEAL DIALYSIS

Inventors : George Wu
Paul Y. Tam
Ian W. French

Examiner : M. Moezie

Group Art Unit: 1614

PRELIMINARY AMENDMENT

June 14, 2000

The Commissioner of Patents
UNITED STATES PATENT OFFICE
2011 South Clark Place
Crystal Plaza 2, Room 1B03
Arlington, Virginia 22202
U.S.A.

Dear Sir:

Applicants respectfully request that the following submissions be entered as a Preliminary Amendment.

IN THE ABSTRACT

Please cancel the abstract presently on file and replace it with the new abstract submitted herein.

IN THE DISCLOSURE

The Examiner is requested to amend the specification by inserting before the first line the sentence ---"This application is a continuation of application number 08/558,472, filed November 16, 1995 (status: allowed)."---

At page 1, line 25, after 'by' and before 'Patent', please insert ---US---.

At page 2, line 21, please delete "(Weiczorowska, K. et al Short Reports?)" and insert ---(Wieczorowska, K. et al. Perit. Dial. Int. 15:81, 1995)---.

At page 2, line 29, please delete "glycosoaminoglycans" and insert ---glycosaminoglycans---.

At page 2, lines 32 to 33, after 'peritoneal' please delete "leucocytes" and insert ---leukocytes---.

At page 4, line 16, after 'removal' please delete ";".

At page 5, line 7, please delete "S. marcescens" and insert ---*S. marcescens*---.

At page 5, line 15, please delete "Patent 5, 011,826" and insert ---US Patent 5,011,826---.

At page 5, line 17, after 'whereas' please insert ---US---.

At page 5, line 19, after 'well' please delete "patent" and insert ---US Patent---.

At page 5, lines 25 to 26, after 'solution' please delete "(Kidney Int 46: 496, 1994: US Patent 4,886,789)" and insert ---(Kidney Int. 46: 496, 1994; US Patent 4,886,789)---.

At page 6, line 33, after 'mixture of' please delete "oligimers" and insert ---oligomers---.

At page 6, line 34, after 'each' please delete "oligimer" and insert ---oligomer---.

At page 7, line 23, after '450 mOsm/L' please delete "(from Patent 4,879,280)" and insert ---(from US Patent 4,879,280)---.

At page 8, line 6, after 'Area' please delete "Coefficicient" and insert ---Coefficient---.

IN THE CLAIMS

Before calculating the fee for filing the instant Continuation Application, please cancel claims 1 to 37 originally filed in United States Patent Application No. 08/558,472 and add new Claims 38 to 82 as follows:

38. A peritoneal dialysis solution comprising at least one amino sugar in an effective amount sufficient to create an osmotic pressure to effect the removal of water by diffusion from the patient's blood across the peritoneal membrane into the solution.

39. The solution of claim 38 wherein the at least one amino sugar is present at a concentration of up to about 5.0% (w/v).

40. The solution of claim 39 wherein the at least one amino sugar is present as a monomer or as an oligomer of 2 to 12 carbohydrate units.

41. The solution of claim 40 wherein the at least one amino sugar is selected from the group consisting of acetylated amino sugars, deacetylated amino sugars and combinations thereof.

42. The solution of claim 41 wherein the acetylated amino sugar is selected from the group consisting of N-acetylglucosamine, N-acetylgalactosamine, N-acetylmanosamine and combinations thereof and the deacetylated amino sugar is selected from the group consisting of glucosamine, galactosamine, mannosamine and combinations thereof.

43. The solution of claim 42 wherein the acetylated amino sugar is N-acetylglucosamine.

44. The solution of claim 43 further comprising at least one electrolyte in an effective amount sufficient to effect the removal of solutes by diffusion from the patient's blood across the peritoneal membrane into the solution.

45. The solution of claim 44 wherein the at least one electrolyte is selected from the group consisting of sodium, calcium, chloride, magnesium, lactate, malate, acetate, succinate, bicarbonate and combinations thereof.

46. The solution of claim 45 further comprising at least one additional agent selected from the group consisting of glucose, iduronic acid, glucuronic acid and combinations thereof.

47. The solution of claim 46 wherein the at least one amino sugar together with the at least one additional agent is present at a concentration of up to about 5.0% (w/v).

48. The solution of claim 47 wherein

(a) the pH is in the range of about 5.0 to about 7.4;

(b) the osmolarity is greater than 280 mOsm/L;

(c) sodium is present at a concentration in the range of about 115 to about 140 mEquiv/L;

(d) calcium is present at a concentration in the range of about 0.6 to about 5.0 mEquiv/L;

(e) chloride is present at a concentration in the range of about 100 to about 145 mEquiv/L;

(f) magnesium is present at a concentration in the range of about 0 to about 2.0 mEquiv/L; and

(g) lactate, malate, acetate, succinate or bicarbonate is present at a concentration in the range of about 30 to about 45 mEquiv/L.

49. A method of performing peritoneal dialysis comprising the introduction of a peritoneal dialysis solution into the peritoneal cavity of a patient, wherein said peritoneal dialysis solution comprises at least one amino sugar, in an effective amount sufficient to create an osmotic pressure to affect the removal of water by diffusion from the patient's blood across the peritoneal membrane into the solution.

50. The method of claim 49 wherein the at least one amino sugar is present at a concentration of up to about 5.0% (w/v).

51. The method of claim 50 wherein the at least one amino sugar is present as a monomer or as an oligomer of 2 to 12 carbohydrate units.

52. The method of claim 51 wherein the at least one amino sugar is selected from the group consisting of acetylated amino sugars, deacetylated amino sugars and combinations thereof.

53. The method of claim 52 wherein the acetylated amino sugar is selected from the group consisting of N-acetylglucosamine, N-acetylgalactosamine, N-acetylmanosamine and combinations thereof and the deacetylated amino sugar is selected from the group consisting of glucosamine, galactosamine, mannosamine and combinations thereof.

54. The method of claim 53 wherein the acetylated amino sugar is N-acetylglucosamine.

55. The method of claim 54 further comprising at least one electrolyte in an effective amount sufficient to effect the removal of solutes by diffusion from the patient's blood across the peritoneal membrane into the solution.

56. The method of claim 55 wherein the at least one electrolyte is selected from the group consisting of sodium, calcium, chloride, magnesium, lactate, malate, acetate, succinate, bicarbonate and combinations thereof.

57. The method of claim 56 further comprising at least one additional agent selected from the group consisting of glucose, iduronic acid, glucuronic acid and combinations thereof.

58. The method of claim 57 wherein the at least one amino sugar, together with the at least one additional agent is present at a concentration of up to about 5.0% (w/v).

59. The method of claim 58 wherein

(a) the pH is in the range of about 5.0 to about 7.4;

(b) the osmolarity is greater than 280 mOsm/L;

(c) sodium is present at a concentration in the range of about 115 to about 140 mEquiv/L;

(d) calcium is present at a concentration in the range of about 0.6 to about 5.0 mEquiv/L;

(e) chloride is present at a concentration in the range of about 100 to about 145 mEquiv/L;

(f) magnesium is present at a concentration in the range of about 0 to about 2.0 mEquiv/L; and

(g) lactate, malate, acetate, succinate or bicarbonate is present at a concentration in the range of about 30 to about 45 mEquiv/L.

60. A method of treating a patient suffering from renal failure comprising the introduction of a peritoneal dialysis solution into the peritoneal cavity of a patient, wherein said peritoneal dialysis solution comprises at least one amino sugar in an effective amount sufficient to create an osmotic pressure to affect the removal of water by diffusion from the patient's blood across the peritoneal membrane into the solution.

61. The method of claim 60 wherein the at least one amino sugar is present at a concentration of up to about 5.0% (w/v).

62. The method of claim 61 wherein the at least one amino sugar is present as a monomer or as an oligomer of 2 to 12 carbohydrate units.

63. The method of claim 62 wherein the at least one amino sugar is selected from the group consisting of acetylated amino sugars, deacetylated amino sugars and combinations thereof.

64. The method of claim 63 wherein the acetylated amino sugar is selected from the group consisting of N-acetylglucosamine, N-acetylgalactosamine, N-acetylmanosamine and combinations thereof and the deacetylated amino sugar is selected from the group consisting of glucosamine, galactosamine, mannosamine and combinations thereof.

65. The method of claim 64 wherein the acetylated amino sugar is N-acetylglucosamine.

66. The method of claim 65 further comprising at least one electrolyte in an effective amount sufficient to effect the removal of solutes by diffusion from the patient's blood across the peritoneal membrane into the solution.

67. The method of claim 66 wherein the at least one electrolyte is selected from the group consisting of sodium, calcium, chloride, magnesium, lactate, malate, acetate, succinate, bicarbonate and combinations thereof.

68. The method of claim 67 further comprising at least one additional agent selected from the group consisting of glucose, iduronic acid, glucuronic acid and combinations thereof.

69. The method of claim 68 wherein the at least one amino sugar, together with the at least one additional agent is present at a concentration of up to about 5.0% (w/v).

70. The method of claim 69 wherein

(a) the pH is in the range of about 5.0 to about 7.4;

(b) the osmolarity is greater than 280 mOsm/L;

(c) sodium is present at a concentration in the range of about 115 to about 140 mEquiv/L;

(d) calcium is present at a concentration in the range of about 0.6 to about 5.0 mEquiv/L;

(e) chloride is present at a concentration in the range of about 100 to about 145 mEquiv/L;

(f) magnesium is present at a concentration in the range of about 0 to about 2.0 mEquiv/L; and

(g) lactate, malate, acetate, succinate or bicarbonate is present at a concentration in the range of about 30 to about 45 mEquiv/L.

71. A method of reducing at least one complication associated with peritoneal dialysis, said method comprising the introduction of a peritoneal dialysis solution into the peritoneal cavity of a patient, wherein said peritoneal dialysis solution comprises at least one amino sugar, in an effective amount sufficient to create an osmotic pressure to affect the removal of water by diffusion from the patient's blood across the peritoneal membrane into the solution.

72. The method of claim 71 wherein the at least one complication associated with peritoneal dialysis is selected from the group consisting of:

(i) morphological and functional deterioration of the peritoneal membrane;

(ii) peritonitis;

(iii) adverse metabolic consequences and related cardiovascular disease;

(iv) protein malnutrition

and combinations thereof.

73. The method of claim 72 wherein the at least one amino sugar is present at a concentration of up to about 5.0% (w/v).

74. The method of claim 73 wherein the at least one amino sugar is present as a monomer or as an oligomer of 2 to 12 carbohydrate units.

75. The method of claim 74 wherein the at least one amino sugar is selected from the group consisting of acetylated amino sugars, deacetylated amino sugars and combinations thereof.

76. The method of claim 75 wherein the acetylated amino sugar is selected from the group consisting of N-acetylglucosamine, N-acetylgalactosamine, N-acetylmanosamine and combinations thereof and the deacetylated amino sugar is selected from the group consisting of glucosamine, galactosamine, mannosamine and combinations thereof.

77. The method of claim 76 wherein the acetylated amino sugar is N-acetylglucosamine.

78. The method of claim 77 further comprising at least one electrolyte in an effective amount sufficient to effect the removal of solutes by diffusion from the patient's blood across the peritoneal membrane into the solution.

79. The method of claim 78 wherein the at least one electrolyte is selected from the group consisting of sodium, calcium, chloride, magnesium, lactate, malate, acetate, succinate, bicarbonate and combinations thereof.

80. The method of claim 79 further comprising at least one additional agent selected from the group consisting of glucose, iduronic acid, glucuronic acid and combinations thereof.

81. The method of claim 80 wherein the at least one amino sugar, together with the at least one additional agent is present at a concentration of up to about 5.0% (w/v).

82. The method of claim 81 wherein

(a) the pH is in the range of about 5.0 to about 7.4;

(b) the osmolarity is greater than 280 mOsm/L;

(c) sodium is present at a concentration in the range of about 115 to about 140 mEquiv/L;

(d) calcium is present at a concentration in the range of about 0.6 to about 5.0 mEquiv/L;

(e) chloride is present at a concentration in the range of about 100 to about 145 mEquiv/L;

(f) magnesium is present at a concentration in the range of about 0 to about 2.0 mEquiv/L; and

(g) lactate, malate, acetate, succinate or bicarbonate is present at a concentration in the range of about 30 to about 45 mEquiv/L.

REMARKS

Claims 38 to 82, as filed herein, are the subject of the instant Continuation Application. Enclosed is a cheque in the amount of $609.00 U.S. which includes $345.00 for the base filing fee of a small entity, $39.00 for 1 independent claim over and above the three allowed, and $225.00 for 25 claims over and above the twenty claims allowed per application. If there should occur an overpayment or an underpayment of fees in respect of this application, the Commissioner is authorized to access Deposit Account Number 08-3255 to make the appropriate adjustments and advised Applicants' Agent.

If the Examiner has any questions, she is respectfully requested to contact Applicants' Agent, Marcelo K. Sarkis at (905) 771-6414 collect at her convenience.

Respectfully submitted,

IVOR M. HUGHES

Marcelo K. Sarkis
Registration No. 37,015

WKS*kdk
Enclosures

TITLE OF INVENTION

A Biocompatible Aqueous Solution For Use in Continuous Ambulatory Peritoneal Dialysis.

SUMMARY OF THE INVENTION

Continuous ambulatory peritoneal dialysis (CAPD) is used to treat end stage renal failure (ESRF) by introducing an osmotically active solution into the peritoneal cavity. Toxic waste products and excess fluid move from the blood into the dialysate solution by diffusion and ultrafiltration across the peritoneum. Osmotic ultrafiltration occurs as a result of the addition of hypertonic concentration of glucose to the dialysing solution, Due to the osmotic gradient between the blood and the CAPD solution the glucose draws water from the blood stream into the peritoneal cavity. The osmotic effect is transient and diminishes as the glucose is absorbed and/or metabolised.

In CAPD the dialysis solution is infused from collapsible plastic bags into the peritoneal cavity where it is retained for a period of time (referred to as the dwell time), after which it is drained and discarded. Generally, 3–5 treatments or exchanges of 1–3 litres each of CAPD solution are carried out daily, with an overnight dwell. The glucose concentration varies between 1.5 and 5% (w/v), with commercial CAPD solutions containing 1.5%, 2.5 or 4.5% glucose, with a high lactate content and various electrolytes which are present in more or less pH ysiologic concentrations. CAPD patients also lose 5–10 grams of protein into the dialysate per day. Commercial CAPD solutions typically have an osmolarity of 300–700 mOsm/L, preferably 350–450 mOsmol/L, as taught by Patent 5,011,826.

Although peritoneal dialysis has some advantages over hemodialysis, including a substantial cost saving, there are several potential complications to CAPD. These include protein loss through the relatively highly permeable peritoneal membrane, absorption and metabolism of the added glucose resulting in weight gain and hyperlipidemia, which is particularly problematic in diabetic patients, who have a high incidence of ESRF (Ong– Ajyooth, L., Transp Proc 26: 2077, 1994).

An average patient absorbs about 150 grams of glucose from the dialysate per day, which for many patients is an excessive source of carbohydrate and results in hyperinsulinemia and hypertriglyceridemia in non–diabetic patients,

which contributes to atherosclerotic disease. This series of events likely contributes to cardiovascular disease which is the most common cause of death among patients with ESRF.

Chronic exposure of the peritoneal membrane to the hypertonic and acidic CAPD solution (pH 5–6.2)can result in a loss of its function as an ultrafiltration membrane, leading to increased permeability of the peritoneal membrane and an increased rate of absorption of glucose from the dialysis solution and a loss of ultrafiltration capability. (Breborowicz et al Advances in Peritoneal Dialysis 8: 11, 1192 and Breborowicz et al Nephron 67: 350, 1994). Peritoneal biopsy samples from patients chronically dialysed with CAPD solutions show a typical epithelial reaction to irritation, mesothelial cell proliferation, as well as a decrease in the number of microvilli which normally line the mesothelial cell surface (Dobbie, J.W., Lloyd, J.K., Gall, C.A. In R. Khamma, K.D. et al Eds. Advances in peritoneal dialysis. Toronto. U of Toronto Press, 3, 1990: Friedlander, M. J Lab Clin Med 122: 639, 1993). A chronic inflammation of the peritoneum is also a consequence of chronic CAPD treatment, possibly related to the acidic nature of the CAPD solution (Lewis, S. & Holmes, C. Periton Dial Int 11: 14, 1991; Beelen, R.H.J. et al In Maher J.F., Winchester, J.F. Eds. Frontiers in peritoneal dialysis. New York: Field, Richj and Associates, 524, 1986; Bos, H.J. et al Nephron 59: 508, 1991), and which leads to healing (Weiczorowska, K. et al Short Reports?). Morphologic changes in the peritoneal structure also occur with chronic CAPD therapy, including fibrosis of the peritoneum (Chaimovitz, C., Kidney Int 45: 1226, 1994). Further, the use of the current relatively acidic and glucose hypertonic CAPD solutions results in a decrease in the function of peritoneal macrophages, again indicating a need for more physiologic and biocompatible CAPD solutions (deFijter, C.W.H. et al Clin Nephrology 39: 75, 1993).

As well, it has been shown that there is a loss of glycosoaminoglycans (GAG's) from the peritoneal membrane which results in a loss of filtration efficiency. It has been suggested that the loss of GAG's from the peritoneal membrane is a result of the increased production of free radicals by activated peritoneal leucocytes (Breborowicz, A. et al Periton Dial Int 11(Suppl): 35a, 1991) or because of a destructive action on interstitial tissue proteins (Fligiel, S.E.G. et al Amer J Pathol 115: 418, 1984). Supplementation of the dialysis fluid with the GAG chondroitin sulphate increases net ultrafiltration due to slower absorption of glucose and fluid from the peritoneal cavity (Advances in Peritoneal Dialysis 8: 11, 1992; Nephron 67: 346, 1994), possibly due to its ability to scavenge free radicals. Other GAG's, such as heparin and dermatan have also been reported

to scavenge free radicals (Hiebert, L., Liu, J.M., Semin Thromb Hemost 17: 42, 1991; Fracasso, A. et al J Amer Soc Neph 5: 75p, 1994). It has also been reported that hyaluronan (formerly known as hyaluronic acid), which also scavenges free radicals, protects the peritoneum from injury resulting from CAPD treatment (Wieczorowska, K. et al Perit. Dial. Int. 15:81, 1995). Supporting this is the finding that the dialysis fluid collected overnight has a higher concentration of hyaluronan than serum. For example, Yung, S. et al (Kidney Int 46: 527, 1994) found that hyaluronan levels increased in the dialysate from ESRF patients with or without peritonitis undergoing CAPD treatment, and that the peritoneal mesothelial cells were the likely source of the hylauronan. Hyaluronan is important in the regulation of cell proliferation during healing. Hyaluronan is a polymer of repeating molecules of N–acetylglucosamine and glucuronic acid; dermatan is composed of repeating units of N–acetylglucosamine and iduronic acid, and chondroitin is made up of glucuronic acid and N–acetylgalactosamine.

Breborowicz and Oreopulos have submitted a PCT patent application (EP–555087–A1) (priority 92US–830721) for the addition of free radical scavengers such as GAG's, including hyaluronic acid degradation products, to CAPD solutions during episodes of peritonitis to prevent against peritonitis–associated inflammatory reactions .

As noted above, N–acetylglucosamine (NAG) is a component of many GAG's. NAG is formed in almost all cells from glucose through a series of biochemical reactions which include the addition of the amine group from glutamine to glucose to form glucosamine, with N–acetylglucosamine being synthesized by way of acetyl–CoA. NAG then is converted to NAG–6–phosphate (which is converted into the epimer of NAG, N–acetyl–mannosamine 6–phosphate which is converted to N–acetylneuraminic acid 9–phosphate which is incorporated into sialic acids, gangliosides and glycoproteins), to NAG–1–phosphate (which is converted into UDP–N–acetylglucosamine (UDP–NAG) which is incorporated into GAG's such as chondroitins and glycoproteins). The UDP–NAG is also converted into GAG's such as hyaluronan and glycoproteins. Thus, NAG is the primary building block of many essential tissue components, whether they are comprised of NAG itself or related amino sugars such as N–acetylmannosamine and N–acetylgalactosamine.

It has been shown that orally administered glucosamine and N-acetylglucosamine (NAG) are absorbed and distributed throughout the body rapidly, and incorporated into tissues and presumably into the GAG's of the body.

These compounds are incorporated into the GAG's of the peritoneal membrane to prevent their depletion thus maintaining the integrity of the peritoneal membrane, and preventing or at least slowing down, the loss of membrane function as an ultrafiltration membrane. Thus, the replacement of part or all of the glucose in the presently available CAPD solutions with amino sugars, especially NAG, should provide a more biocompatible peritoneal dialysis solution, while providing the necessary osmotic effect required for the removal of excess water and also removal of waste substances by solvent drag from patients with ESRF undergoing CAPD treatment. Unlike glucose, which is utilized by almost all microorganisms as a source of energy, the amino sugars are relatively less metabolized and not as likely to support microbial growth thus reducing the tendency for patients undergoing chronic CAPD treatment to develop peritonitis, a common and serious adverse event associated with CAPD treatment. Because of the rapid removal; of NAG and other amino sugars from the systemic circulation by way of their incorporation into GAG's and various amino sugar containing tissue components the extent of metabolism into lipids is significantly reduced, thus reducing the risk of obesity, protein malnutriton, dyslipidemia and hypertriglyceridemia, hyperinsulinemia etc and the related adverse metabolic consequences.

In order for NAG and related amino sugars to be useful as osmotic agents in CAPD solutions they must have a high chemical purity similar to that which would be required for use in pharmaceutical products, which means a minimum purity of 98.5%. NAG which is of this purity can be manufactured by two methods. The first is the acid digestion of crude chitin, which is a linear polymer of repeating units of NAG obtained from crab and shrimp shells and other crustaceans, followed by isolation of the deacetylation of the individual NAG units to glucosamine. The glucosamine is isolated and crystallized to a high level of purity and then is reacetylated using acetic anhydride to N–acetylglucosamine, which is precipitated and recrystallized from alcohol, such that its purity is greater than 98.5%. The second method of manufacturing NAG, and the preferred method, is to obtain NAG from dried crustacean shell or crude chitin by direct enzymatic digestion with an ensemble of enzymes including chitinase and chitobiase, which degrades the chitin polymer of NAG into disaccharide units of chitobiase and then into monomer units of NAG directly, without having to undergo any organic synthetic step. The NAG is recrystallized from alcohol to a high degree of purity from ethanol. The enzymes required for this process are secreted into the growth media of various microorganisms, especially Serratia marcescens. Thus this method of manufacture not only provides NAG of a suitable purity for use in CAPD solutions but also permits the relatively inexpensive production of NAG as the chitin

or crustacean shells can be added directly to the cell–free growth medium from a culture of S. marcescens and the NAG readily isolated from the medium after a suitable reaction period. By varying the length of the enzymatic reaction time the production of polymers of varying units of NAG can be produced, which can be further refined and isolated as specific molecular weight entities by way of separation using available chromatographic techniques, and which can be isolated, crystallized and further purified by recrystallization using methods familiar to those skilled in the methods of carbohydrate chemistry isolation and purification.

Patent 5, 011,826 teaches that CAPD solutions can use galactose alone or with glucose in varying ratios as the osmotically active agents, whereas Patent 4,879,280 teaches that disaccharides such as lactose, saccharose, cellobiose etc can be used similarly, both together with suitable electrolyte additives. As well patent 4,879,280 also shows the use of trisaccharides, oligosaccharides and polysaccharides of a molecular weight less than 400,000 such as raffinose, starch, inulin, pectin, dextrans, hydroxy–ethyl starch (HES) and the like. For example, colloidal polymers of glucose of 4–250 glucose units long and with an weight average molecular weight of about 16,200 and a number average molecular weight of 5,800 has been clinically evaluated as component of a CAPD solution (Kidney Int 46: 496, 1994: US Patent 4,886,789). The osmolality of a 7.5% solution of this glucose polymer, called Icodextrin, was 282 mOsm/kg and had a pH of 5.3. However, neither the available scientific literature nor the available patents teach the use of polymers or oligimers of amino sugars such as N–acetylglucosamine, N–acetylmannosamine or N–acetylgalactosamine and the like as the osmotically active components of CAPD solutions, which are the subject of the present invention.

Since the effectiveness of intraperitoneal dialysis depends on the presence of a hypertonic solution and osmolarity depends on the number of molecules in solution, large molecules such as GAG's provide little of value to the osmotic effect of the CADP solution, and the dialysis solution must still contain excess glucose. Since N–acetylglucosamine and related amino sugars, as well as the other sugar and/or acidic carbohydrates making up the GAG's have molecular weights similar to that of glucose, they would be osmotically active. Therefore, the inclusion of amino sugars, particularly N–acetylglucosamine, in a CAPD solution at concentrations ranging from 0.5 to 5%, with or without the presence of glucose, will provide an effective dialysis solution while being more biocompatible with the peritoneal membrane and thus preventing or slowing down the morphologic and functional deterioration of the peritoneal membrane and extending the time over

which ESRF patients may effectively use CAPD treatment. This provides several benefits, including substantial cost saving to the health care system by reducing the need for expensive hemodialysis, a lower rate of peritoneal infection for patients receiving CAPD treatment, a lesser risk of cardiovascular disease due to a reduction in the lipid changes typical of use of currently available CAPD solutions, and a better quality of life for such patients.

Currently marketed CAPD solutions have the following typical composition per 100 mL of solution. Dextrose anhydrous 1.5, 2.5 or 4.25 plus Sodium Chloride 567 mg, Sodium lactate 392 mg, Calcium Chloride dihydrate 23.9 mg and Magnesium Chloride hexahydrate 15.2 mg. On a milliequivalence basis this represents 132 mEq Na/L, 3.24 mEq Ca/L, 1.5 mEq Mg/L, 101.75 mEq Cl/L and 36 mEq lactate/L. Alternately, the solution may contain malate, acetate or succinate in place of lactate. The solution typically has an osmotic pressure of 347 mOsmol/L.

The CAPD solution of this invention is intended to provide similar electrolyte levels as currently available CAPD solutions, except that the osmotically active carbohydrate composition is different, being composed of acetylated and deacetylated amino sugars including N–acetylglucosamine, glucosamine, N–acetylgalactosamine, galactosamine, N– acetylmannosamine, mannosamine each alone, or in combination at varying concentrations or with varying concentrations of glucose, or oligomers of N–acetylglucosamine, N–acetylmannosamine, N–galactosamine, galactosamine, mannosamine, and glucosamine such that they are comprised of at least 2 carbohydrate units and not more than 12 units. The composition may be a mixture of oligimers of varying amounts of each oligimer either alone or in combination with each other. As well the CAPD solutions of this patent may contain additional osmotically active agents in varying proportions to the acetylated and deacetylated amino sugars such acidic carbohydrates which are also incorporated into the tissue glycosoaminoglycans (GAG's) such as glucuronic acid and iduronic acid.

In animal models of inflammatory bowel disease the colon becomes fribrotic, as does the peritoneum as a result of chronic intraperitoneal dialysis. The administration of a solution of NAG into the bowel of rats in which a chemically induced inflammatory bowel reaction with bowel wall thickening or fibrosis occurs, reduces in a dose dependent manner the fibrotic reaction to the inflammatory stimulus (Table 1). It is to be expected that in a similar manner NAG will prevent the development of fibrosis of the peritoneum in CAPD patients.

In addition to glucose CAPD solutions typically also contain a suitable number and quantity of electrolytes such that a more less physiologic solution is obtained. For example, lactate is included as a base substitute. Its absorption and metabolism will correct metabolic acidosis. Sodium is usually included at a concentration slightly lower to that found in plasma, or 132–137 mM/L, to promote sodium removal. Similarly, chloride is usually included in the CAPD solution at physiologic strengths of 100–110 mM/L. .

The normal osmolarity of blood is approximately 280 mOsm/L, so that a CAPD solution must have a greater osmotic value than this if it to be effective as a dialysis solution, and preferably it should have an osmotic pressure of 300–700 mOsm/L, and more specifically 310–560, or in a more limited range, of 350 to 450 mOsm/L (from Patent 4,879,280).

Table 1

COLON FIBROSIS (AS MEASURED BY WEIGHT(gm) OF 8 cm OF COLON)	
INTRARECTAL ADMINISTRATION	**MEAN ± SEM**
Control (20 mg TNB* in 0.25 mL Ethanol)	2.301 ± 0.222
25 mg NAG/kg BWt 1 hr before TNB/EtOH	1.669 ± 0.142
50 mg NAG/kg BWt 1 hr before TNB/EtOH	1.339 ± 0.155
100 mg NAG/kg BWt 1 hr before TNB/EtOH	1.150 ± 0.068

* TNB = trinitrobenzenesulfonic acid

In experiments in which rats were dialyzed for 4 hours with Hanks Balances salt solution with either glucose or N–acetylglucosamine added at a concentration of 75 mM or 214 mM, at a pH of 7.35 – 7.4. The net utrafiltration was calculated as the difference between the drained volume of dialysate after 4 hours dwell time in the peritoneal cavity and the infused volume (20 mL) of the dialysis fluid. As well, the concentration of urea and creatinine in the blood and the dialysis fluid were measured. Permeability of the peritoneal membrane to urea and creatinine, expressed as the Mass Transfer Area Coefficicient which was calculated according to the method of Krediet et al (Blood Purif 4: 194, 1986). The results, given in the Table below, clearly demonstrate that NAG results in a statistically significant increase in net ultrafiltration as well as peritoneal clearance of urea without increasing albumin or total protein loss into the dialysis fluid. In

addition, the inclusion of NAG in the dialysate fluid stimulated the synthesis of hyaluronic acid, as shown by the more than 100% increase in amount of hyaluronic acid secreted in the dialysis fluid compared to the glucose treated rats. These in vivo experiments clearly demonstrate that NAG is a more effective osmotic agent than glucose when used for peritoneal dialysis.

	Glucose **75 mM** (N=11)	**NAG** **75 mM** (N=14)	**Glucose** **214 mM** (N=11)	**NAG** **214 mM** (N=13)
Net Ultrafiltration (mL/4 hrs)	-0.44 ± 2.0	–0.11 ± 1.6	11.45 ± 1.2	**14.45 ± 1.6***
Mass Transfer Area Coef for Urea (mL/min)	0.344 ± 0.13	0.287 ± 0.13	0.212 ± 0.07	0.262 ± 0.15
Peritoneal Clearance of Urea (mL/min)	18.8 ± 2.2	18.4 ± 2.1	26.9 ± 2.0	**30.0 ± 2.2****
Total Protein Dialysate/Serum Ratio (%)	4.3 ± 1.0	4.4 ± 0.6	2.8 ± 0.4	3.1 ± 0.5
Albumin Dilaysate/Serum Ratio (%)	4.0 ± 1.6	3.9 ± 1.2	1.6 ± 0.6	2.0 ± 0.9
Hyaluronic Acid in Dialysate Fluid (ug/L)	103 ± 21	**226 ± 93***	91 ± 31	**217 ± 96*****

* = statistically significant ('t'–test), $p < 0.001$

** = statistically significant ('test'–test), $p < 0.01$

*** = statistically significant, $P < 0.002$

The stimulation of hyaluronic acid by N-acetylglucosamine was confirmed in tissue culture of human mesothelial cells.

As many changes can be made to the embodiments of the invention without deporting from the scope of the invention, it is intended that all material herein be interpreted as illustrative of the invention and not in a limiting sense.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A peritoneal dialysis solution which comprises a water solution with a pH compatible with the intended use of the product, with electrolytes, including sodium, chloride, calcium and magnesium of a suitable and compatible compositions and one or a combination of acetylated or deactylated amino sugars, such as glucosamine, N–acetylglucosamine, galactosamine, N–acetylgalactosamine, mannosamine, N–acetylmannosamine as monomers or oligomers of 2 to 12 carbohydrate units alone or in combination with glucose and/or sodium lactate, malate, acetate, succinate and/or iduronic acid and/or glucuronic acid.

2. The solution of claim 1 in which the pH is in the range of 5 – 7.4 and the sodium concentration is present in the range of 115 – 140 mEquiv/L, calcium is present in the range of 0.6 mEquiv/L, chloride is present in the range of 100 – 145 mEquiv/L, magnesium is present in the range of 0 –2 mEquiv/L, lactate, malate, acetate or succinate in the range of 30 – 45 mEquiv/L.

3. The solution of claim 1 in which the osmotically active agent is and amino sugar taken from the following group of compounds of glucosamine, N–acetylglucosamine, galactosamine, N–acetylgalactosamine, mannosamine or N–acetylmannosamine.

4. The solution of claim 3 in which the osmotically active agents are present at a concentration of 0.5 – 5.0 % (w/v).

5. The solution of claim 3 of which the osmotically active agents are present at the concentrations specified in claim 4 together with glucose at a concentration of 0.5 to 5.0% (w/v).

6. The solution of claim 1 in which the osmotically active agents are present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

7. A peritoneal dialysis solution comprising an effective amount of an acetylate or deacetylated amino sugar and/or combinations thereof.

8. The peritoneal dialysis solution of claim 7 wherein the amino sugar is N-acetylglucosamine (NAG).

9. The peritoneal dialysis solution of claim 7 wherein the amino sugar is selected from glucosamine, N–acetylglucosamine, galactosamine, N–acetylgalactosamine, mannosamine, N–acetylmannosamine as monomers or oligomers of 2 to 12 carbohydrate units alone or in combination with glucose and/or sodium lactate, malate, acetate, succinate and/or iduronic acid and/or glucuronic acid.

10. The solution of claim 7 in which the pH is in the range of 5 – 7.4 and the sodium concentration is present in the range of 115 – 140 mEquiv/L, calcium is present in the range of 0.6 mEquiv/L, chloride is present in the range of 100 – 145 mEquiv/L, magnesium is present in the range of 0 –2 mEquiv/L, lactate, malate, acetate or succinate in the range of 30 – 45 mEquiv/L.

11. The solution of claim 8 in which the pH is in the range of 5 – 7.4 and the sodium concentration is present in the range of 115 – 140 mEquiv/L, calcium is present in the range of 0.6 mEquiv/L, chloride is present in the range of 100 – 145 mEquiv/L, magnesium is present in the range of 0 –2 mEquiv/L, lactate, malate, acetate or succinate in the range of 30 – 45 mEquiv/L.

12. The solution of claim 9 in which the pH is in the range of 5 – 7.4 and the sodium concentration is present in the range of 115 – 140 mEquiv/L, calcium is present in the range of 0.6 mEquiv/L, chloride is present in the range of 100 – 145 mEquiv/L, magnesium is present in the range of 0 –2 mEquiv/L, lactate, malate, acetate or succinate in the range of 30 – 45 mEquiv/L.

13. The solution of claim 7 in which the amino sugar is taken from the following group of compounds of glucosamine, N–acetylglucosamine, galactosamine, N–acetylgalactosamine, mannosamine or N–acetylmannosamine.

14. The solution of claim 9 in which the amino sugar is taken from the following group of compounds of glucosamine, N–acetylglucosamine, galactosamine, N–acetylgalactosamine, mannosamine or N–acetylmannosamine.

15. The solution of claim 7 in which the amino sugar is present at a concentration of 0.5 – 5.0 % (w/v).

16. The solution of claim 8 in which the amino sugar is present at a concentration of 0.5 – 5.0 % (w/v).

17. The solution of claim 9 in which the amino sugar is present at a concentration of 0.5 – 5.0 % (w/v).

18. The solution of claim 10 in which the amino sugar is present at a concentration of 0.5 – 5.0 % (w/v).

19. The solution of claim 11 in which the amino sugar is present at a concentration of 0.5 – 5.0 % (w/v).

20. The solution of claim 12 in which the amino sugar is present at a concentration of 0.5 – 5.0 % (w/v).

21. The solution of claim 13 in which the amino sugar is present at a concentration of 0.5 – 5.0 % (w/v).

22. The solution of claim 14 in which the amino sugar is present at a concentration of 0.5 – 5.0 % (w/v).

23. The solution of claim 7 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

24. The solution of claim 9 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

25. The solution of claim 10 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

26. The solution of claim 11 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

27. The solution of claim 12 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

28. The solution of claim 13 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

29. The solution of claim 14 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

30. The solution of claim 15 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

31. The solution of claim 16 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

32. The solution of claim 17 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

33. The solution of claim 18 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars

comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

34. The solution of claim 19 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

35. The solution of claim 20 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

36. The solution of claim 21 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

37. The solution of claim 22 in which the amino sugar is present as monomers of the amino sugars specified or are oligomers of these amino sugars comprising 2 – 12 carbohydrate units, alone or together with glucose as detailed in claim 5.

ABSTRACT

The present invention relates to a peritoneal dialysis solution comprising at least one amino sugar in an effective amount sufficient to create an osmotic pressure to effect the removal of water by diffusion from the patient's blood across the peritoneal membrane into the solution. In one embodiment the at least one amino sugar is selected from the group consisting of acetylated amino sugars, preferably N-acetylglucosamine, deacetylated amino sugars and combinations thereof.

Declaration, Power Of Attorney And Petition

We, **GEORGE WU, PAUL Y. TAM and IAN W. FRENCH**, declare that we are citizens of CANADA residing at c/o #3 Gerald Street, Willowdale, Ontario, Canada, M2L 2M4; that we have reviewed and understood the contents of the attached Specification, including the Claims as amended by any amendments referred to and we verily believe we are the original, first and joint inventors of the invention A BIOCOMPATIBLE AQUEOUS SOLUTION FOR USE IN CONTINUOUS AMBULATORY PERITONEAL DIALYSIS described and claimed in the attached specification; that we do not know and do not believe that this invention was ever known or used in the United States of America before our invention or discovery thereof, or patented or described in any printed publication in any country before our invention or discovery thereof, or more than one year prior to this application; that this invention was not in public use or on sale in the United States of America for more than one year prior to this application; that this invention or discovery has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by us or our legal representatives or assigns more than twelve (12) months before this application; that we acknowledge our duty to disclose information of which we are aware which is material to the examination of this application in accordance with 37 CFR 1.56(a), and that no application for patent or inventor's certificate on this invention or discovery has been filed by us or our representatives or assigns in any country foreign to the United States of America except as follows:

Canadian Patent Application Serial No. 2,155,910 filed on August 11, 1995 from which application convention priority is claimed

And I hereby appoint IVOR M. HUGHES, NEIL H. HUGHES, and MARCELO K. SARKIS, carrying on business at 175 Commerce Valley Drive West, Suite 200, Thornhill, Ontario, L3T 7P6, Canada, Registration Number 27,759, Registration Number 33,636, and Registration Number 37,015, as my attorney or agent to prosecute this application and to transact all business in the Patent Office connected therewith.

Wherefore we pray that Letters Patent be granted to us for the invention or discovery described and claimed in the foregoing specification and claims, and we hereby subscribe our names to the foregoing specification and claims, declaration, power of attorney, and this petition.

We declare further that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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